

for Medicare payment under certain provider contracts, access by the Secretary, upon written request, and the Comptroller General, and their duly authorized representatives, to certain contracts for services and to books, documents, and records necessary to verify the costs of the services. The contracts affected are those between providers and their subcontractors, and between the subcontractors and organizations related to the subcontractor by control or common ownership. It also specifies the criteria by which HHS will determine whether to request access to books, documents, and records.

§ 420.301 Definitions.

For purposes of this subpart—

Books, documents, and records means all writings, recordings, transcriptions and tapes of any description necessary to verify the nature and extent of the costs of the services provided by the subcontractor.

Common ownership means that an individual or individuals possess significant ownership or equity in the subcontractor and the entity providing the services under the contract.

Contract for services means a contract through which a provider obtains the performance of an act or acts, as distinguished from supplies or equipment. It includes any contract for both goods and services to the extent the value or cost of the service component is \$10,000 or more within a 12-month period.

Control means that an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions of policies of an organization.

Provider means a hospital, skilled nursing facility, home health agency, hospice or comprehensive outpatient rehabilitation facility, or a related organization (as defined in §413.17 of this chapter) of any of these providers.

Related to the subcontractor means that the subcontractor is, to a significant extent, associated or affiliated with, owns, or is owned by, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies.

Subcontractor means any entity, including an individual or individuals, that contracts with a provider to sup-

ply a service, either to the provider or directly to a beneficiary, for which Medicare reimburses the provider the cost of the service. This includes organizations related to the subcontractor that have a contract with the subcontractor for which the cost or value is \$10,000 or more in a 12-month period.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984; 51 FR 34833, Sept. 30, 1986]

§ 420.302 Requirement for access clause in contracts.

(a) *Applicability.* This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(1)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is \$10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth \$10,000 or more over a 12-month period.

(b) *Requirement.* Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(1)(I)(ii) of the Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, CMS will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid

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nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984]

§ 420.303 HHS criteria for requesting books, documents, and records.

HHS will generally request books, documents, and records from a subcontractor only if one of the following situations exists and the question cannot satisfactorily and efficiently be resolved without access to the books, documents, and records:

(a) HHS has reason to believe that the costs claimed for services of the subcontractor are excessive or inappropriate.

(b) There is insufficient information to judge the appropriateness of the costs.

(c) There is a written accusation with suitable evidence against the provider or subcontractor of kickbacks, bribes, rebates, or other illegal activities.

(d) There is evidence of a possible nondisclosure of the existence of a related organization.

§ 420.304 Procedures for obtaining access to books, documents, and records.

(a) *Contents of the request.* Requests for access will be in writing and contain the following elements:

(1) Reasonable identification of the books, documents, and records to which access is being requested.

(2) Identification of the contract or subcontract in which costs are being questioned as excessive or inappropriate.

(3) The reason that the appropriateness of the costs or value of the services of the subcontractor in question cannot be adequately or efficiently determined without access to the subcontractor's books and records.

(4) The authority in the statute and regulations for the access requested.

(5) To the extent possible, the identification of those individuals who will be visiting the subcontractor to obtain

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access to the books, documents, and records.

(6) The time and date of the scheduled visit.

(7) The name of the duly authorized representative of HHS to contact if there are any questions.

(b) *Subcontractor response to a request for access to books, documents, and records.* (1) The subcontractor will have 30 days from the date of a written request for access to books, documents, and records to make them available in accordance with the request.

(2) If the subcontractor believes the request is inadequate because it does not fully meet one or more of the required elements in paragraph (a) of this section, the subcontractor must advise the requesting organization of the additional information needed.

(i) The subcontractor must notify the requesting organization within 20 days of the date of the request that it was improperly completed.

(ii) The subcontractor must make the books, documents, and records available within 20 days after the date of the requesting organization's response.

(3) If the subcontractor believes, for good cause, that the requested books, documents, and records cannot be made available as requested with the 30-day period under paragraph (b)(1) of this section, the subcontractor may request an extension of time within which to comply with the request from the requesting organization. The requesting organization may, at its discretion, grant the request for an extension, in whole or in part, for good cause shown.

(4) The subcontractor must make the books, documents, and records available during its regular business hours for inspection, audit, and reproduction.

(5) If HHS asks the subcontractor to reproduce books, documents, and records, HHS will pay the reasonable cost of reproduction. However, if the subcontractor reproduces books, documents, and records as a means of making them available, the subcontractor must bear the cost of the reproduction and no Medicare reimbursement will be made for that purpose.